From: Alan Lewis
To: AMS - GMO Labeling
Subject: Comment concerning the The National Bioengineered Food Disclosure Standard - below and attached
Date: Sunday, July 16, 2017 6:47:11 PM
Attachments: Proposed Rule Questions Under Consideration.pdf

Proposed Rule Questions Under Consideration

The National Bioengineered Food Disclosure Standard was enacted on July 29, 2016. AMS has two years to establish a national standard and the procedures necessary for implementation. Below are 30 questions for consideration by interested stakeholders. USDA will use this input in drafting a proposed rule. There will also be an opportunity for interested parties to comment on the proposed rule during the rulemaking process.

Input related to the questions below should be sent to GMOlabeling@ams.usda.gov

1. What terms should AMS consider interchangeable with 'bioengineering'? (Sec. 291(1))

Context: The disclosure standard would be a mechanism to inform consumers about their food. AMS is considering the advantages and disadvantages of allowing the use of other terms to provide for disclosure.

> AMS should not attempt to describe bioengineering methods. The number of methods and technologies now used to bioengineer flora and fauna are at least doubling each year. There is no practical way to describe all bioengineering practices in a way that will encompass all current and future methods and technologies except by what it is not.
>
> Instead, AMS should describe conventional methods of promoting preferred trait expression using whole genome selection and employing the original (natural) genetic transfer/reproductive process of the species. Any process outside of classical whole-gene trait selection methods would therefore be considered bioengineering.

2. Which breeding techniques should AMS consider as conventional breeding? (Sec. 291(1)(B))

Context: AMS is considering what would be defined as modifications that could otherwise be obtained through conventional breeding because these modifications would be exempt from mandatory disclosure.

> Conventional methods of promoting the expression of particular traits has used selection and propagation of individual plants, animals and insects that express desired traits while suppressing undesired traits. In conventional breeding methods the

organism's original (natural) method of genetic transfer/reproduction is allowed to proceed, which ensures that its full, complete and integrated genetic encoding remains active and intact.

Conventional breeding may rely on technology to identify and select for particular genetic markers, genes, traits, and other proxies for a desired trait or set of traits. The use of leading edge and experimental technologies to identify methods to accelerate trait development and expression should be considered part of conventional breeding as long as the organism's original (natural) genetic transfer/reproductive process is the only process by which genetic material is recombined.

Applying conventional breeding techniques to previously bioengineered organisms should not result in that organism being identified as conventionally bred.

3. Which modifications should AMS consider to be found in nature? (Sec. 291(1)(B))

Context: AMS is considering what would be defined as modifications that could otherwise be found in nature because these modifications would be exempt from mandatory disclosure.

Only modifications that are the result of the organism's original (natural) genetic transfer/reproductive process should be considered to be found in nature. If a modification is the result of a bioengineering process, and claims to be bio-identical to a modification that "would" or "could" result from the original (natural) reproductive process, that modification should not be considered to be found in nature.

Bioengineered organisms of any kind (those not created using original (natural) genetic transfer/reproductive processes to recombine genetic material) should not be considered to be found in nature even when, over time, they can be readily found in nature due to drift, migration, wilding, or other causes.

4. Will AMS require disclosure for food that contains highly refined products, such as oils or sugars derived from bioengineered crops? (Sec. 291(1)(A))

Context: Many processed foods may contain ingredients derived from bioengineered crops, such as highly refined oils or sugars that contain undetectable levels of bioengineered genetic material such that they are indistinguishable from their non-engineered counterparts. AMS is considering whether to require disclosure for foods containing those derived ingredients that may be undetectable as bioengineered.

Consumers no longer identify a food derived from bioengineering based on whether or not it contains identifiable genetically modified material. The argumentation framework espoused by bioengineering proponents since the 1970's continues to rely on "food safety" as the primary characteristic by which bioengineered food should be judged by consumers. However, this was then, and remains now, a false framework. Consumers and independent scientists have abandoned it.

To a corporate entity, the presence of bioengineered organisms in one of the food products produces or handles can represent a particular set of values and outcomes:

"progress" | "innovation" | "shareholder value" | "protected market position" |

> “protectable intellectual property assets” | “scientific breakthrough” | “new capabilities” | “lower costs” | “return on investment” | “one more piece of the puzzle” | “less variability” | “greater uniformity” | “cost stability” | “revenue and profit”

For an individual employee of the same corporation, the presence of bioengineered organisms in one of the food products produces or handles can represent a particular set of values and outcomes:

> “Job security | “prestige and advancement” | “better job prospects” | “chance to publish” | “another patent” | “feeding the world” | “part of a breakthrough” | “team effort” | “more funding for my research” | “historic progress” | “helping farmers” | “a better world” | etc.

For farmers, the presence of bioengineered organisms in the food products they produce can represent a particular set of values and outcomes:

> “low margins” | “forced to scale up” | “one buyer, one price” | “my farm is a food desert” | “am I being poisoned?” | “high cost technology” | “I can’t go back to conventional or organic” | “everyone wants a piece of me” | “no profit except to sell the farm” | “we never had blight before” | “what is my neighbor spraying now:” | “I need a safety net more than ever” | “USDA payments here yet?” | “dependent on export trade deals” | “my kids won’t be farmers” | “these weeds won’t die” | “what concoction will they come up with next?” | etc.

For consumers, the presence of bioengineered organisms in the food products they consume can represent a particular set of values and outcomes:

> “unknown consequences” | “antibiotic resistance” | “herbicide residues” | “loss of wildlife and insect habitat” | “loss of biodiversity” | “fewer food choices” | “concentrated feeding operations” | “loss of rural vitality” | “corporate control of the food supply” | “monoculture blights” | “loss of smallholder family farms” | “unstudied affects on health” | “genetic transfer in the gut biome” | “glyphosate in fetal blood and breast milk” | etc.

5. Although the Law states that the definition of bioengineering shall not affect any other definition, program, rule, or regulation of the Federal government, could there be potential areas of confusion between the definition of bioengineering as used in the Law and other similar terms used by the Federal government? If so, what are the potential remedies that could be added to this regulation to alleviate any confusion between this definition and others by the Federal government? (Sec. 292(b))

Context: AMS recognizes that other Federal agencies have different terms to describe organisms created through recombinant DNA techniques. AMS is considering areas of potential overlap or confusion over terms, as well as potential language to add to this regulation to ensure the term bioengineering does not affect any other definition, program, rule, or regulation.

The Law was written to obfuscate key issues and concepts at a time of great technological upheaval. It needs to be fixed by identifying what methods retain intact and complete genomes, and allow mutations and recombinations only via the specie's natural gene transfer/reproductive processes. At present, consumers consider all food products to be bioengineered in some way unless it is certified organic or certified by the NonGMO project.

6. Meat, poultry, and egg products are only subject to a bioengineered disclosure if the most predominant ingredient, or the second most predominant ingredient if the first is broth, stock, water, or similar solution, is subject to the labeling requirements under the Federal Food, Drug, and Cosmetic Act. How will AMS determine the predominance of ingredients? (Sec. 292(c))

Context: AMS is considering how to evaluate predominance to determine how the Law will apply to multi-ingredient food products.

These animals are routinely administered antibiotics, vaccines and feed/forage produced with genetically engineered organisms. The resulting animal products should all be labeled as bioengineered foods. The law was written to evade consumer disclosure of this and other production practices. Consumers are not stupid. This obfuscation will be discovered and the backlash will be fierce.

7. How should AMS craft language in the regulations acknowledging that the Law prohibits animal products from being considered bioengineered solely because the animal consumed feed products from, containing, or consisting of a bioengineered substance? (Sec. 293(b)(2)(A))

Context: AMS is considering regulatory language similar to the wording in the Law and if the Agency should provide clarity that food derived from any animal, including invertebrates such as crickets or bee products, would not require disclosure as a bioengineered food solely because their nutrition came from food with bioengineered ingredients.

The effects of bioengineered feed are well enough understood to conclude that gene transfer takes place within the microbiome of the digestive tract of the animal. Antibiotics in particular may cause reactions within the biome that permanently compromise the quality and content of the edible parts of the animal. Since glyphosate (the primary active ingredient in many herbicides used for weed control genetically engineered crops) is patented as a **full spectrum antibiotic** for soil, human and animal applications, it's clear that its presence in animal feed causes de facto secondary bioengineering in these animals. In addition, Bt toxin for rootworm control is produced systemically by genetically engineered corn varieties; the insecticide is now generally present is human blood, urine, fetal cord blood and breast milk. Finally, the presumption that small amounts of glyphosate, Bt and similar substances have only minor effects on human and animal health no longer holds true: peer reviewed studies now show that it is indeed *minute* amounts that can cause the most cell damage and subsequent permanent developmental deficiencies.

Therefore, although the law was written to obfuscate these issues, the AMS should require that

labeling on foods containing ingredients derived from conventional animals disclose which bioengineered feed, growth promoters and medicines were fed or administered to the animal.

8. What is the amount of a bioengineered substance present in a food that should make it be considered bioengineered? (Sec. 293(b)(2)(B))

Context: The Law authorizes the Secretary to determine the amount of a bioengineered substance present in food in order for the food to be disclosed as a bioengineered food. The amounts of a bioengineered substance that may be present in food in order for the food to be a bioengineered food might be determined in a variety of ways: if a bioengineered substance is near the top of the list of ingredients, by determining the percentage of bioengineered ingredients in a food product, or by listing any ingredient that was produced through bioengineering, among others. AMS is considering how to determine the amount of bioengineered food or ingredient needed for a product to require a bioengineered disclosure, as well as the advantages and disadvantages of various methods.

> This is not the right question. The methods, practices, processes, adjuvants, and pesticides used to support genetically engineered crops and livestock are themselves the problem. Whether or not identifiable genetic material ends up on a consumer's plate is irrelevant. Removing or obfuscating genetically modified material will only antagonize consumers. In addition, allowing any amount of residual genetically modified material will only cause an gradual increase in the amount of residual material allowed. This is demonstrably true both in genetic engineering monitoring efforts like the NonGMO Project, which as consistently raised its allowable background contamination levels as contamination of the food supply increases. Similarly, the EPA continues to increase the allowed residue of pesticides associated with genetically engineered crops because residues continue to increase substantially.
>
> A food or food ingredient is either genetically engineered or it is not. Because the law allows producers to hide behind a scannable image on the food packaging rather than stating on the package that the food is partially genetically modified, the AMS can require full disclosure of the status of every ingredient in the food product on the web page linked to the scannable symbol on the package. The AMS should ignore measures of residue and require manufacturers to disclose whether each ingredient is produced with genetic engineering or not.
>
> Testing for genetic markers that may serve as proxies for genetic engineering of some part of a food, food ingredient, processing aid or excipient allows for continued obfuscation. Labs can use tests with limited sensitivity; reference materials can be outdated or incomplete. Tests can be run which will not identify the markers being looked for. It's faster, cheaper and more accurate to maintain records of genetic modifications for incoming food and other substances when purchased from the supply chain.

9. Should AMS consider more than one disclosure category? (Sec. 293(b)(2)(D))

Context: AMS is considering if it should develop various categories for disclosure and if it should differentiate between those products that a) are bioengineered, b) contain ingredients that are bioengineered, or c) contain ingredients derived from bioengineered crops or animals.

Additionally, AMS is considering the creation of a set of disclosures for a category of bioengineered foods for those products that, due to changes in sourcing, include bioengineered ingredients for part of the year, and non-bioengineered ingredients for other parts of the year. AMS is considering the advantages and disadvantages, based on cost, clarity, and other factors, of using a single disclosure category or multiple disclosure categories.

> This issue has been responded to in prior responses. The AMS will continue to hide the presence of genetically engineered material unless it requires supply chain verification, rather than testing for residues, of genetically modified ingredients. Because there is unlimited space available for disclosures via the manufacturer's web site (via the scannable symbol on the packaging), all genetically engineered substances should be identified. Often this information will be lot-specific. Since good manufacturing practices require careful recordkeeping of recipes and actual ingredient sources by lot, it will not be a significant burden for lot level disclosure to be posted on the website when necessary.
>
> The AMS should require uniform disclosure of all genetically modified food, ingredients, processing aids and excipients by the manufacturer. The AMS should require all foods that are partially produced with genetic engineering to disclose all genetically modified ingredients.

10. What other factors or conditions should AMS consider under which a food is considered a bioengineered food? (Sec. 293(b)(2)(C))

Context: AMS must develop a process to help stakeholders determine whether a food is subject to bioengineered disclosure. AMS anticipates the process would include considering factors such as: whether a food contains a substance that has been modified using recombinant in vitro DNA techniques (Sec. 291(1)(A)), whether the modification could not be obtained through conventional breeding or found in nature (Sec. 291(1)(B); Question 2 and 3), , and whether a food requires disclosure based on the predominance of ingredients (Sec. 292(c); Question 6), among others. The outcomes of these determination requests might be publically posted on a Web site. The process to implement Sec. 293(b)(2)(C) is not intended to be an investigation or enforcement process (see Questions 26-29); instead, the implementation would likely be framed for manufacturers or developers of bioengineered food or ingredients who have a question on whether their food is subject to disclosure. AMS is considering the factors to be considered, the way to inform the public about the outcome of the requests, and ideas regarding the process to be used to make the determination.

> Any process that recombines genetic material outside of the original (natural) genetic transfer/reproductive process of the species is bioengineering. The original (natural) reproductive process ensures that the integrated functioning of the entire, whole genome remains intact and unadulterated. The use of technologies to identify individual plants and animals with specific traits or other genetic profiles is no bioengineering as long as the original (natural) genetic transfer/reproductive process of the species is used to recombine genetic material.
>
> The AMS must take care to define the term "stakeholder" during the development of these rules and guidelines. The term stakeholder is sometime used to describe only the direct economic participants, similar to the term "industry". However, every human

being on the planet is a stakeholder in the unfolding of genetic engineering technology. The decisions made by AMSs to develop a regulatory framework for this rule will permanently and fundamentally change the future of the planet. Natural species will disappear permanently, and new species with unintended (or intended) traits will actively reproduce themselves. The agricultural and food production systems will be force to adapt to genetic engineering, whether the global stakeholders are aware of or agree with that outcome. It appears that the AMS is using the term "stakeholders" to describe the patent holders and patent users of genetically engineered plants, animals, and other organisms. The value system of these economic stakeholders is just that: economic. Their ability to properly weigh risk is foreclosed by their desire for economic gain. This is a fundamentally and permanently dangerous way to decide policy. The AMS must foster, include and emphasize all stakeholders, especially those who will be the ultimate test subjects of this dangerous experiment.

11. Could AMS consider whether a type of food is considered a bioengineered food under the determination process? (Sec. 293(b)(2)(C))

Context: AMS is considering if it could exclude certain food types such as medical food and dietary supplements, among others from requiring disclosure as bioengineered.

Consumers are aware of and concerned about the unidentified, unstudied and unknown consequences of bioengineering to human health, animal welfare, environmental pollution, and biodiversity. The AMS should allow and support the ability of consumers to choose to avoid bioengineered products of all types, including medical food and dietary supplements. (In turn, the AMS should ensure that non-bioengineered products remain available and unaffected by efforts to commercialize bioengineering technology.) The risks and reward value systems of consumer stakeholders are different from those of corporate stakeholders. The AMS should allow and support the ability of consumers to consider and evaluate the potential risks and benefits of each product that may be produced with bioengineering, including medical food and dietary supplements. The science on the risk and safety of bioengineered production systems and the resulting products is in fact settled: independent scientists acknowledge that the complexity of life and genetic coding far beyond our present capabilities to understand or control.

12. If a manufacturer chooses to use text to disclose a bioengineered food, what text should AMS require for a text disclosure? (Sec. 293(b)(2)(D))

Context: Currently, some food manufacturers use language compliant with the Consumer Protection Rule 121 from the State of Vermont to identify their food products as bioengineered ("Produced with Genetic Engineering," "Partially Produced with Genetic Engineering," or "May be Produced with Genetic Engineering"). AMS is considering whether to allow manufacturers to continue using these disclosures under the new national bioengineered disclosure standard and if their language is appropriate. Further, AMS is considering what phrases could be used as a text disclosure for bioengineered food that consumers would find informative, truthful, and not misleading.

AMS is also considering whether there should be one standard text disclosure language, or whether manufacturers should be allowed flexibility to choose from more than one acceptable phrase and where the bioengineered food disclosure should be placed on food packages.

The uniform text “Produced with Genetic Engineering,” “Partially Produced with Genetic Engineering,” or “May be Produced with Genetic Engineering” should be the only text allowed in order to avoid consumer confusion. *However, the purpose of this text must be to notify the consumer that additional information is available online.* The additional information must easy to find, presented in a consistent manner across all websites, and should not require searching for the information beyond entering in the URL of the information page manually or by scanning a symbol on the packaging.

13. If a manufacturer chooses to use a symbol to disclose a bioengineered food, what symbol should AMS require for disclosure? (Sec. 293(b)(2)(D))

Context: AMS needs to ensure that the symbol designed for the bioengineered disclosure is not disparaging toward bioengineering. As with the text disclosure, AMS must develop criteria for placement of the symbol to ensure consumers can readily locate the symbol, the symbol is scalable for different sized packages, and the symbol is a meaningful representation of bioengineered foods. AMS is considering what the symbol should look like and guidance on its use.

The AMS should require a single uniform type of scannable symbol on the food packaging. No other symbol should be allowed, so as to avoid consumer confusion.

HOWEVER, the AMS should develop a unique symbol (“bioengineered symbol” that appears on manufacturer web sites to signal to site visitors where access information related to genetically engineered foods in cases where they have not scanned a symbol on the food package but have otherwise entered the site looking for this information. The clickable bioengineered symbol should appear on the manufacturer’s web site on the each page that describes the features, ingredients or nutritional content of each product.

The goal of establishing the use of a common online bioengineered symbol to identify where to find information about bioengineering is to avoid parking informational pages where they cannot be found using conventional navigation from a site’s home page. “Dark pages” can only be accessed by entering in the exact URL (manually or my scanning a symbol on the food package). It is imperative that the AMS require manufacturer web sites to provide easily found links and other navigation so consumers can find out about the qualities of food products without delay or frustration.

Note that the bioengineered symbol will need to bear the initials “GMO”. The alternatives such as “GE” for genetic engineering, GM for genetically modified or “BIO” for bioengineered will cause confusing due to their widespread use to identify General Electric and General Motors (major global corporations) and Biologique (the designation used in the European Union to describe certified organic food. The commenter strongly recommends against attempting to establish a new identifier for genetically modified food. “GMO” is already recognized and accepted across the globe. An attempt (even a well-intentioned one) to circumvent the use of GMO will be seen as more obfuscation. For those economic stakeholders that would prefer a new less politically charged identifier, the AMS should remind them that it is only a matter of time before their next turn of phrase is equally suspect among informed consumers.

14. If a manufacturer chooses to use an electronic or digital link to disclose a bioengineered food, what requirements should AMS implement for an electronic or digital link disclosure? (Sec. 293(b)(2)(D))

Context: See Questions 23-25.

15. Should AMS specify in the regulations the type of electronic or digital disclosure manufacturers, e.g. QR code, can use to disclose bioengineered food? What steps should AMS take if an electronic or digital disclosure method becomes obsolete? (Sec. 293(b)(2)(D))

Context: AMS recognizes that disclosure technologies may quickly surpass regulations. AMS is considering what terms will ensure the regulations keep pace with technological changes and how AMS can notify stakeholders about changes in technology as they occur. AMS is also considering what the most appropriate electronic or digital disclosure technologies are currently and how to deal with obsolete technologies.

> The goal of establishing the use of a common online symbol to identify where to find information about bioengineering is to avoid "parking" informational pages on web sites where they cannot be found using conventional navigation from a site's home page or other pages. "Dark pages" can only be accessed by entering in the exact URL (manually or by scanning a symbol on the food package). It is imperative that the AMS require manufacturer web sites to provide easily found links and other navigation so consumers can find out about the qualities of food products without delay or frustration.

16. What kind of text, symbol, or electronic or digital disclosure should AMS require for bioengineered food that is not purchased from a grocery store shelf, such as food for sale in bulk (such as fresh produce in a bin or fresh seafood at a fish counter), in a vending machine, or online? (Sec. 293(b)(2)(D))

Context: In some situations, disclosures may not be easily located when such products are on display for sale. AMS is considering disclosure practices for these and other non-conventional purchasing or packaging scenarios.

> Any bulk item that MAY be genetically engineered (the technology exists and the product or its constituents has been approved for sale) must be labeled as such UNLESS the seller has documentation that the product is certified nonGMO or USDA Organic or similar.

17. The Law offers special provisions for disclosure on very small or small packages. How should AMS define very small or small packages? (Sec. 293(b)(2)(E))

Context: AMS is considering if it should mirror FDA's treatment of very small and small packages for nutrition labeling.

a. In 21 CFR 101.9(j)(13)(i)(B), FDA defines small packages as those with less than 12 square inches in total surface area available to bear labeling.

b. FDA also has allowances for packages that have less than 40 square inches of total surface are available to bear labeling.

In the case of small or very small packages, the AMS should require the use of a single common graphic symbol that signals to the consumers that information on bioengineered ingredients is available online (the "bioengineered symbol"). All food packaging sold at retail must already carry the manufacturer's identity, which can include its web site address if the site contains readily found contact information. On small and very small packaging, the AMS should require the web address (URL) to appear on the package near the bioengineered symbol. HOWEVER, the identical bioengineered symbol must appear on the web page to which the URL is directed, and that symbol must in turn link directly to the required bioengineering disclosures.

18. What are the reasonable disclosure options AMS should provide for food contained in very small or small packages? (Sec. 293 (b)(2)(E))

Context: AMS is considering the disclosure standards for very small or small packages. FDA regulates nutrition labeling on very small or small packages differently. For example:

a. Could disclosure requirements for very small packages be met by providing an address or phone number where consumers could obtain the information?

b. Could disclosure requirements for small packages be met by providing abbreviated text disclosure or a Web site address where consumers could obtain disclosure information?

In the case of small or very small packages, the AMS should require the use of a **single uniform graphic symbol** that signals to the consumers that information on bioengineered ingredients is available online (the "bioengineered symbol"). All food packaging sold at retail must carry the manufacturer's identity, which can include its web site address. On small and very small packaging, the AMS should require the web address (URL) to appear on the package near the bioengineered symbol. HOWEVER, the identical bioengineered symbol must appear on the web page to which the URL is directed, and that symbol must in turn link directly to the required bioengineering disclosures.

The commenter recognizes that this suggestion for small and very small packages appears to be in conflict with the suggestion that only a scannable symbol appear on larger packaging. Note that requiring a scannable symbol on larger packaging encourages consumers to pursue the information available online, and that the same "bioengineered symbol" contemplated for small and very small packages would also appear on the pages to which the scannable symbol directs consumers. In this way, the consumers remain within the same contextual framework whether they are scanning, searching a web site, or entering in the URL printed on a small or very small package.

19. How should AMS define small food manufacturers? (Sec. 293(b)(2)(F))

Context: AMS is considering using regulatory language similar to that of other Federal government agencies that already define small businesses. For example:

a. FSIS considers small businesses to be those with 500 or fewer employees and that

produces 100,000 pounds or less of annual production of a single product, including single forms of meat such as sausage, bulk, patties, links, consumer product, etc., when determining exemptions from nutrition facts labeling (9 CFR 317.400 (a)(1)(ii)).

b. FDA has several small business definitions with respect to food labeling rules, such as: i) retailers with total annual gross sales of $500,000 or less, 21 CFR 101.9(j)(1) and (18); ii) food and dietary retailers with annual gross sales of foods or dietary supplement products of $50,000 or less, 21 CFR 101.9(j)(1) and 101.36(h)(1); and iii) businesses that employ fewer than 100 full-time workers that produce a product that sells fewer than 100,000 units throughout the United States in a 12-month period, 21 CFR 101.9(j)(18) and 101.36(h)(2).

AMS is considering the advantages or disadvantages of these definitions of small food manufacturers for the bioengineered food disclosure regulations.

The $500,000 or less figure, as defined by FSMA, would appear to adequate to protect very small producers. The cost to add labeling or signage in the case of a potentially genetically modified product is minimal, therefore exclusions and waivers should be minimized.

20. For disclosures by small food manufacturers, what is the appropriate language indicating that a phone number provides access to additional information? (Sec. 293(b)(2)(F)(ii)(I))

Context: AMS is considering using language in Sec. 293(d)(1)(B) of the Law.

A phone number in conjunction with the “bioengineered symbol.”

21. The Law excludes restaurants and similar retail food establishments from disclosure requirements. How should AMS define similar retail food establishment to exclude these establishments from the requirements of the regulation? (Sec. 293(b)(2)(G)(i))

Context: AMS is considering how to treat establishments that sell food ready for human consumption, such as institutional food service, delicatessens, or catering businesses. In its regulations for Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments (21 CFR 101.11), FDA defines restaurant or similar retail food establishment and restaurant-type food

For FSIS, the Federal Meat Inspection Act (FMIA) provides for the mandatory inspection of commercial meat and meat products. The FMIA and implementing regulations do, however, provide exemptions from the continuous inspection provisions for retail operations and restaurants (9 CFR 303.1(d)(2)).

NOP also defines retail food establishment in its regulations (7 CFR 205.2).

AMS is using this information as it considers definitions for restaurants and similar retail

establishments, with the understanding that these definitions will be used to determine what types of retail establishments are excluded from the requirements of the Law.

> The AMS should use the definitions established by the FDA to determine which restaurants and other food establishments are required to post nutrition labeling. In this case, the bioengineering disclosure requirements should be similar to those proposed for small and very small packaging applications. The menu or other reference document should include a bioengineered symbol next to appropriate menu items, with a human readable shortened URL next to it. Interested consumers will be notified that some part of the menu item was produced with bioengineering (via the symbol) and can type in the shortened URL to learn more. As an alternative, each item can carry an asterisk, which referenced on the same page the shortened URL to obtain more information. The URL should be used alongside the "bioengineered symbol".

22. How should AMS define very small food manufacturers to exclude these manufacturers from the requirements of the regulation? (Sec. 293(b)(2)(G)(ii))

Context: See Question 19. AMS could use definitions similar to how other Federal agencies define very small businesses, and is considering definitions to distinguish small food manufacturers (Question 19) and very small food manufacturers, with understanding that very small food manufacturers would be excluded from the requirements of the Law.

> A very small business should simply use the language May be produced with genetic engineering unless it can prove otherwise. There is no cost to do so, so there should be no exclusion.

23. Is there other equivalent on-package language that AMS should consider to accompany an electronic or digital disclosure besides "Scan here for more food information"? (Sec. 293(d)(1)(A))

Context: The word 'scan' may or may not be relevant for each type of electronic or digital disclosure in the present or in the future. AMS is considering if it should issue guidance to identify equivalent language as technology changes and what that equivalent language would be.

> A human readable URL should be printed directly below the scannable symbol. The human readable URL can be a shorted URL such as those provided by bit.ly and other providers. This will allow consumers without internet enabled phones or phones with symbol scanning capability to manually access the bioengineering disclosures from a computer.

24. How should AMS ensure that bioengineered food information is located in a consistent and conspicuous manner when consumers use an electronic or digital disclosure? (Sec. 293(d)(2))

Context: AMS is considering requiring the same information associated with the text disclosure as the requirement language for an electronic or digital disclosure (See Question 12). Further, AMS is trying to determine how various disclosure options affect the amount

and type of information available to consumers. AMS is also determining if there should be requirements or guidance on what size text would ensure the information is conspicuous to ensure the food information is located in a consistent and conspicuous manner when electronic or digital disclosure is accessed.

The AMS should define what constitutes the "primary product page" on the web site or web sites of the manufacturer of a food product. **The scannable symbol on the food packaging must redirect the consumers to the primary product page for the product in question.** The symbol may not direct the consumer to a dark page that is otherwise not readily discoverable by a visitor to the web site. The text regarding bioengineered contents of the product must appear on this page in a style and size similar to that on the rest of the page. The bioengineering disclosure may appear anywhere on the page, as long as a link in the top readable portion of the page ("above the fold" on a large screen or "top of the page" on a small screen where the use must scroll down to read) contains a clickable link that jumps down to the bioengineering disclosure lower on the page. The bioengineering disclosure must be on the primary product page of the web site; it cannot reside on a page or location that requires the site visitor to click to another page or to a page on another web site. The clickable link may take the form of highlighted or underlined text or the "bioengineering symbol" discussed elsewhere in this comment.

All manufacturers maintain a list of the ingredients used to make each product and/or contained in each product. The ingredient list should appear in on the primary product page. Next to each ingredient, the manufacturer should post the approved statement regarding bioengineering. Often this information will be in some amount of doubt. The manufacturer may use an asterisk to identify ingredients that "may be produced with genetic engineering" IF the footnote immediately follows the ingredient list and is in bold type of at least the same size as the listed ingredients.

General bioengineering disclosure pages should be avoided. Consumers make purchase and consumption decisions on a product by product basis. A manufacturer with hundreds of products, most of which use, say, genetically engineered soy lecithin, may desire to state "all soy lecithin used in our products may be genetically engineered" on a general disclosure page. While this is acceptable, it does not eliminate the need to disclose the same information on the primary product page on the web site. The scannable symbol, and the human readable URL below it, must be directed to the primary product page and not a general disclosure page.

25. How should AMS ensure that an electronic or digital disclosure can be easily and effectively scanned or read by a device? (Sec. 293(d)(5))

Context: AMS is aware that electronic or digital disclosures need to be effective, that requirements will vary for each specific type of electronic or digital disclosure, and that the technology for electronic or digital disclosure may change faster than AMS will be able to update its regulations. AMS is determining how to address these issues given the variety of electronic or digital disclosures currently available in the marketplace, along with the specifications for these disclosures to be used effectively in a retail setting.

The Law was written to substantially impede the ability of consumers to easily access

the information posted on a manufacturer's web site. To overcome this deficiency, the symbology used should be 1) required to be used in a uniform format and same general location by all manufacturers on all food products 2) free to download, activate and use the software or application needed to ready the symbols 3) used in conjunction with a general graphic symbol, that appears prominently on the manufacturer's web site, in which is embedded a URL link to the information on bioengineering for a particular product, in case the consumer is unable to scan the bioengineering symbol itself, and 4) require a human readable web site address be printed below the scannable symbol to facilitate manual access to the bioengineering information. The address in item 4 can be a shortened URL such as provided by Bit.Ly.

26. What types of records should AMS require to be maintained to establish compliance with the regulations? (Sec. 293(g)(2))

Context: Each person or entity subject to the mandatory disclosure requirement would be required to maintain and make available to the Secretary records that establish compliance with the Law. Typically, record keeping requirements include those for the records required to be kept, the place of maintenance of such records, the record retention period, and what it means for AMS to have adequate access to and inspection of such records.

Under current FSIS regulations, records must be maintained at a place where business is conducted, except that if business is conducted at multiple places of business, then records may be maintained at a headquarters office. When the business is not in operation, records should be kept in accordance with good commercial practices. For FSIS, records are required to be maintained for a 2-year period. The maintenance time for FDA records vary from 6 months through up to 2 years.

AMS is considering what recordkeeping requirements for persons subject to the Law would be most appropriate.

Current Good Manufacturing Practices under FSMA and other statutes already require full supply chain information be available for review in case of a recall for food safety reasons, misbranding allegations, or other enforcement actions. As part of this existing process, each supplier should request and maintain written verification of the bioengineering status of each ingredient or material acquired for use in the manufacture of its products. Although it may vary somewhat by state, they typical retention time for food related records is just beyond the three year statute of limitations for liability claims. A three year time frame would give the AMS adequate time to identify potential problems, request records and other information as part of an investigation, and escalate enforcement action before the relevant records are subject to deletion or destruction.

27. How should AMS obtain information related to potential non-compliance with these regulations? Is there information USDA should request prior to conducting an examination of non-compliance? (Sec. 293(g))

Context: AMS is considering what tools could be used to identify potential non-compliance and enforce compliance with the regulations. AMS is considering the types of information needed to verify compliance with the Law and the most optimal way to obtain such

information.

28. What are the rules of practice for a hearing? (Sec. 293(g)(3)(B))

Context: AMS is considering the appropriate procedures for audits and other compliance actions, including opportunities for hearing. AMS is considering this aspect for the rules of practice and other options regarding a prospective hearing and internal adjudication process.

29. How should AMS make public the summary of any examination, audit, or similar activity? (Sec. 293(g)(3)(C))

Context: AMS is considering if the results and findings of any examination, audit, or similar activity should be posted after the notice and opportunity for a hearing described under Sec. 293(g)(3)(B). AMS is also considering how it should make summaries of the examination, audit, or similar activity public.

> Yes. The AMS should promote full transparency to allow for a robust debate, among all stakeholders and acknowledge all value systems, about the nuances of implementing and enforcing the law.

30. What should the requirements for imports into the United States of products covered by the Law/regulation be? (Sec. 294(a))

Context: AMS is considering how the disclosure requirements should be applied to imported products.

> Full compliance with all labeling requirements for US produced foods and foods imported for sale in the United States.

Alan Lewis
Govt Affairs, Food and Ag Policy, Organic Compliance, Supply Chain Integrity
(303)601-9451 mobile

Alan Lewis
Director of Special Projects
alewis@naturalgrocers.com
12612 W Alameda Pkwy
Lakewood, CO 80228
Telephone: 303-986-4600 x80108
Fax: 303-986-1891

Join us on

www.NaturalGrocers.com
